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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/090,038

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James R. Komorowski

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,038

Applicant(s)

KOMOROWSKI ET AL.

Examiner

Frank I Choi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 23-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 23-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The finality of the rejection of the last Office action is withdrawn in view of Applicant's response (12/20/2004) and in order to set forth new and/or additional grounds for rejection. Accordingly, the amendment (12/20/2004) has been entered.

Claim Objections

Claims 16-18,50-52 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. According to Applicant's arguments the transitional phrase "consisting essentially of" excludes any bioactive substance other than chromium complex and biotin. Nicotinic acid reduces cholesterol in humans and has a short term hypoglycemic effect depending on the dose. See Urberg et al., pg. 605 (The Journal of Family Practice (1988). Rudzite et al. (Advances in Experimental Medicine and Biology (1999)) discloses that picolinic acid in vitro induced the elevation of cholesterol/phospholipid ratio and cholesterol concentration (See entire document, especially Abstract). It appears that both nicotinic acid and picolinic acid are bioactive, as such, the phrase "consisting essentially of" according to Applicant's interpretation of the same would exclude nicotinic acid and picolinic acid. The addition of nicotinic and/or picolinic acid in the dependent claims expands the scope of the subject matter from a previous claim.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,4-6,8,10-13,17,19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rath (US Pat. 6,693,129).

Rath expressly discloses a method of treating high LDL and high triglycerides by administering a composition containing biotin and chromium glycinate falling within the scope of applicant's claims (Column 6, lines 34-68, Column 7, Column 8, lines 1-20).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978). See also *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 190 USPQ 461, 463 (CCPA 1976) (held

that there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics). "A `consisting essentially of' claim occupies a middle ground between closed claims that are written in a `consisting of' format and fully open claims that are drafted in a `comprising' format." PPG Industries v. Guardian Industries, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder Co. v. E.I. duPont de Nemours & Co., 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. v. Calco, Ltd., 7 USPQ2d 1097 (Fed. Cir. 1988).

However, for search and examination purposes, absent a clear indication in the specification of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 48 USPQ at 1355 ("PPG could have defined the scope of the phrase `consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.").

When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)("Although `consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . .

[rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by "consisting essentially of language.").

Applicant's interpretation of the effect of the transitional phrase "consisting essentially of" is misplaced. *American Machine & Foundry Company v. Liggett & Myers Tobacco Co*, 121 USPQ 133 (DC NJ 1959). (herein after "American Machine") did not hold that materials that had a complimentary or beneficial effect are excluded by the transitional phrase "consisting essentially of". The basic and novel characteristic of the invention in *American Machine* was that the composition approximate the natural leaf in terms moisture, tensile strength and thickness in order to provide the same handleability qualities as tobacco leaf in the manufacture of cigarettes. The court determined that the addition of the substances resulted in changes in tensile strength and chemically altered the locust bean gum molecules such that it had significantly higher water resistance (*American Machine* at Pgs. 135,138). In *PPG Industries Inc. v. Guardian Industries Corp.* 48 USPQ2d 1351 (CAFC 1998) (herein after "PPG Industries") the basic and novel characteristics of the glass were color, composition and light transmittance (*PPG Industries* at pg. 1354). The holding in *PPG Industries* turned on the determination that the term "SO₃" in the specification of the patent at issue did not include iron sulfide which was present in the alleged infringing composition and effected the color and transmission of the glass and that evidence was presented showing that even small changes in the color or transmittance tinted glass would be considered material such that the jury's determination as to materiality was

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supported (PPG Industries at pg. 1356). See *AK Steel Corp. v. Sollac*, 68 USPQ2d 1280, 1283, 1284 (CA FC 2003). See also *Winter v. Fujita*, 53 USPQ2d 1234, 1239, note 6 (BdPatApp&Int 1999) (“consisting essentially” could have been used instead of Applicant defining “comprising” in the specification to include the possible use of other components so long as it did not impair the effects of the present invention.” ; *In re Herz and Willis*, 190 USPQ 461, 463 (CCPA 1976) (“consisting essentially of” excludes materials that would have a deleterious effect). As such, addition of folic acid, L-arginine and L-carnitine would not materially effect the basic and novel characteristics of the invention as they provide the same or similar benefits desired by Applicant in the claimed invention. If Applicant’s arguments were valid than Applicant’s independent claims would exclude any food which might naturally or because of the preparation process included a substance, for example folic acid, L-arginine or L-carnitine. Further, Applicant’s interpretation of “consisting essentially of” would exclude the addition of nicotinic and picolinic acid which is claimed in several of the dependent claims as they appear to have a beneficial effect on the effects of chromium and/or biotin. See discussion of *Urberg et al.* and *Rudzite et al.* above.

Applicant addresses a 103 rejection over *Rath*, however, the rejection herein is an inherency rejection under 35 USC102/103. The *Graham v. John Deere* factors are not applicable in an inherency-based rejection. As such, Applicant’s argument relative to obviousness do not appear to overcome the rejection. In any case, as indicated above, Applicant’s evidence, in fact, supports the inclusion of the additional ingredients. Contrary to Applicant’s argument, Examiner has never opined that it would have been obvious to omit the other thirty-five ingredients. There is no need to omit the thirty-five other bioactive ingredients as Applicant has not shown that they

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are excluded by the phrase "consisting essentially of." Even if it was necessary, the other prior art discloses the benefits of selecting chromium complex and biotin. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) ("Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.).

Claims 1-5, 8-13,19,20,23-28,30,31-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jensen (US Pat. 5,194,615).

Jensen expressly discloses administration of food in the form of a 2.2 g tablet containing 0.0003 mg of biotin which is fed to rats in combination with 10 ppm of chromium in the form of chromium chloride or chromium nicotinate in drinking water which resulted in the reduction of glucose, cholesterol and triglyceride levels falling within the scope of applicant's claims (Column 10, lines 35-68, Column 11, lines 1-55).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978). See also *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 1-20, 23-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarty (US Pat. 5,789,401) or McCarty (US Pat. 5,929,066), each in view of de la Harpe et al. (US Pat. 5,948,772), Jensen (US Pat. 5,194,615), Brand-Miller (Am. J. Clin. Nutr. (1994)), Reddi et al. (Life Sciences (1988)), McCarty (Medical Hypotheses (1999)), Boyle et al. (Southern

Medical Journal (1977)) Mossop (Central African Journal of Medicine (1991)), Dokusova et al. (Kardiologiiia (1972)) and McCleary (US Pat. 6,579,866).

McCarty (US Pat. 5,789,401) teaches a pharmaceutical composition containing chromic tripicolinate and biotin wherein the ratio of the chromic tripicolinate to biotin is between about 100:1 and 5:1 (w/w) (Column 2, lines 42-45). It is taught that the for reducing hyperglycemia and stabilizing the level of serum glucose between about 1000 and 10000 micrograms per day, preferably between about 1,000 and 5,000 micrograms, of chromium tripicolinate in combination with between about 1 mg and 200 mg per day, advantageously between 5mg and 50 mg, of biotin having a synergistic effect in a pharmaceutically acceptable carrier and that the same may be orally or parenterally administered (Column 2, lines 23-57). It is taught that for oral administration that the composition may be provided as an aqueous or oil suspension, dispersible powder or granule, emulsion, syrup or elixir (Column 3, lines 6-9).

McCarty (US Pat. 5,929,066) teach a pharmaceutical composition containing chromic tripicolinate and biotin wherein the ratio of the chromic tripicolinate to biotin is between about 2:1 and 1:200 (w/w) (Column 2, lines 48-54). It is taught that the for reducing hyperglycemia and stabilizing the level of serum glucose between about 50 and 1000 micrograms per day, preferably between 500 and 1000 microgram, of chromium tripicolinate in combination with between about 25 micrograms and 200 mg per day, preferably between 1 mg and 100 mg, of biotin begin selected to provide a greater than additive effect, i.e. synergistic effect, in a pharmaceutically acceptable carrier and that the same may be orally or parenterally administered (Column 2, lines 28-65). It is taught that for oral administration that the composition may be

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provided as an aqueous or oil suspension, dispersible powder or granule, emulsion, syrup or elixir (Column 3, lines 13-16).

de la Harpe et al. teach that chromium supplements, such as chromium tripicolinate, reduce hyperglycemia, stabilize serum glucose and control blood serum lipid levels, including the lowering of undesirably high blood serum LDL-cholesterol levels and the raising of blood serum HDL-cholesterol levels (Column 2, lines 30-38). It is taught that addition of nicotinic acid and/or picolinic acid facilitates the absorption of other ingested chromium in the human diet (Column 5, lines 1-15). It is taught that chromic polynicotinate has the same uses as chromium tripicolinate (Column 2, lines 38-41, Column 5, lines 9-16). It is taught that for oral administration, the composition may be incorporated into a aqueous or oil suspension, dispersible powder or granule, emulsion, syrup or elixir or the components may also be administered separately (Column 5, lines 30-37). It is disclosed that chromium depletion results in biologically ineffective insulin and compromised glucose metabolism and that under these conditions the body must rely primarily on lipid metabolism to meet its energy requirements, resulting in the production of excessive amounts of acetyl-CoA and ketone bodies (Column 1, lines 25-31). It is disclosed that some of the acetyl-CoA is converted to increased cholesterol biosynthesis, resulting in hypercholesterolemia (Column 1, lines 31-33). It is disclosed that diabetes mellitus is characterized in large part by glycosuria, hypercholesterolemia and often ketoacidosis and that the accelerated atherosclerotic process seen in diabetics is associated with hypercholesterolemia (Column 1, lines 33-36).

Jensen teaches that chromium nicotinate is effective in reducing triglycerides (Column 10, lines 35-68, Column 11, lines 1-56). It is taught that compositions containing the same can

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be administered orally, as liquid solutions or suspensions or powders and that the same can be administered independently or as a food supplement, including incorporating the same into a food or drink, or the same can be administered parenterally (Column 7, lines 13-29, Column 14, lines 3-6).

Brand-Miller teaches that glycemic index (GI) a concept that ranks foods on the basis of their acute glycemic impact (Pg. 747S). It is taught that unlike high-fiber diets, low GI diets are “user friendly” (Pg. 750S). It is taught that measurable clinical gains are associated with diets in which that GI has been reduce by at least 11 units, by exchanging 50% of the carbohydrate from high- to low-GI food (Pg. 750S).

Reddi et al. discloses that biotin treatment lowered post-prandial glucose levels and improved tolerance to glucose and decreasing insulin resistance (See entire reference, especially Abstract).

McCarty (Medical Hypotheses (1999) discloses that the combination of biotin and chromium picolinate to treat insulin resistance, improve beta-cell function, enhance postprandial glucose uptake by both liver and skeletal muscle and inhibit excessive hepatic glucose production (See entire references, especially abstract).

Boyle et al. disclose that natural sugars and grains contain substantial concentrations of Cr, sufficient to facilitate the metabolism of these high carbohydrate foods, however, almost all Cr is removed during the refining process (Pg. 1449).

Mossop discloses that persons eating unrefined maize meal had a lower fasting blood glucose level with a smaller rise in glucose and insulin levels 60 minutes after a glucose load than did persons eating highly refined cereals (Pg. 371).

Dokusuva et al. disclose that administration of biotin reduced the level of cholesterol in the blood of patients with atherosclerosis and essential hyperlipidemia (Abstract).

McCleary discloses treating insulin resistance, hyperinsulinemia, hypertriglyceridemia, low HDL syndrome, small dense LDL syndrome and postprandial hyperlipidemia by administering a composition containing biotin and chromium, such as chromium picolinate, thereby improving insulin sensitivity, decreasing triglyceride and VLD levels, decreasing postprandial hyperlipidemia, decreasing the concentration of small dense LDL particles and elevating existing low levels of HDL (Column 1, lines 13-22, Column, 4, lines 4-10, 39-54, Column 5, lines 29-35, 47-54, Table I, Table II, Claims 5-7, 17-19).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

Contrary to Applicant's arguments, the McCarty references do disclose the combination of two bioactive agents, chromium and biotin. Further, as indicated above, biotin alone and the combination of biotin and chromium reduce post-prandial glucose levels. The prior art, as indicated above, suggests that foods rich in chromium facilitate the metabolism of higher

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carbohydrates and reduce rise in glucose and insulin levels after ingested versus foods in which chromium is low or has been refined away. Since the prior art discloses that chromium and biotin will control post-prandial glucose and the incorporation of supplements into food, it would have been well within the skill of one of ordinary skill in the art to add biotin and chromium to a food product. Further, since glycemic index is a measurement of glycemic impact of the food, by incorporating biotin and chromium, given its effects on post-prandial glucose, one of ordinary skill in the art would expect that the glycemic index of the food product would lower versus the food product without the biotin and chromium.

Contrary to Applicant's arguments, the prior art does disclose a link or causal connection between insulin resistance and compromised glucose metabolism and hypercholesterolemia. See de le Harpe et al. above. As such, one of ordinary skill in the art would expect that biotin, which is known to be effective in controlling diabetes, insulin resistance and compromised glucose metabolism, would be effective in treating certain types of hypercholesterolemia in which insulin resistance and compromised glucose metabolism is the cause of the hypercholesterolemia. In any case, regardless of the mechanism, the prior art specifically discloses that biotin is effective in reducing hypercholesterolemia. Further, the prior art teaches a composition containing both biotin and chromium which is used to lower LDL and triglycerides and increase HDL. As such, the prior art does disclose that biotin is effective in treating both insulin resistance and treating hypercholesterolemia.

Rath is no longer part of the rejection herein, however, as indicated in the discussion of Rath above "consisting essentially of" does not exclude any other bioactive agent which has a material beneficial effect on the effects of chromium and/or biotin.

Applicant amends the claims by adding the limitation "synergistically" and cites to Figures 2 and 14 and pages 15 and 25 of the Specification for supported of this synergistic effect. However, the evidence of synergy is not commensurate in scope with the breath of the claims as only specific amounts are tested and only glucose uptake and HDL-cholesterol change are shown. None of the claims recite that the synergistic effect is increase HDL-cholesterol level and/or increase in glucose uptake. Further, the claims broadly claim a synergistically effective amount and even the specified ranges in the dependent claims greatly exceed the amounts tested.

Applicant provides no evidence that one of ordinary skill in the art would expect that any other amount of biotin and chromium would have synergistic effects. Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In *re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Claims were directed to a process for removing corrosion at "elevated temperatures" using a certain ion exchange resin (with the exception of claim 8 which recited a temperature in excess of 100C). Appellant demonstrated unexpected results via comparative tests with the prior art ion exchange resin at 110C and 130C. The court affirmed the rejection of claims 1-7 and 9-10 because the term "elevated temperatures" encompassed temperatures as low as 60C where the prior art ion exchange resin was known to perform well. The rejection of claim 8, directed to a temperature in excess of 100C, was reversed.). See also *In re Peterson*, 315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not

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evidence unexpected results for the entire claimed range of about 1-3% rhenium); In re Grasselli, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalysts containing sodium with the prior art. The court held this evidence insufficient to rebut the prima facie case because experiments limited to sodium were not commensurate in scope with the claims.).

Furthermore, the synergistic effect is not recited, as such, the claims include within their scope a synergistic effect which is different from the effect set forth in the preamble of the claim. Even assuming the evidence of synergy is commensurate in scope with the claims, both McCarty '066 and McCarty '401 disclose the combination of biotin and chromium complex results in synergistic effects and, more, importantly, disclose amounts of biotin and chromium which fall within the scope of the specified ranges claimed by Applicant for biotin and chromium as being synergistic (McCarty '066, Column 2, lines 56-65; McCarty '401, Column 2, lines 49-57) . Since Applicant's applicant's arguments relative to biotin are unpersuasive, as indicated above, Applicant's evidence of synergy is not unexpected. See Ex parte The NutraSweet Co., 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991) (Evidence showing greater than additive sweetness resulting from the claimed mixture of saccharin and L-aspartyl-L-phenylalanine was not sufficient to outweigh the evidence of obviousness because the teachings of the prior art lead to a general expectation of greater than additive sweetening effects when using mixtures of synthetic sweeteners.).

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Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

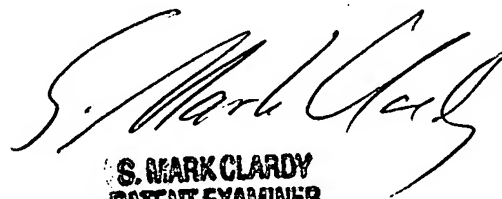
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

February 19, 2005



S. MARK CLARDY
PATENT EXAMINER
GROUP 1200
1616